PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Robert E. Burgmeier, Richard L. Goodin, Joseph Delaney Jr., and Larry Peterson**
Application No.:	**10/749821**
Filed:	**December 31, 2003**
For:	**MEDICAL DEVICE WITH VARYING PHYSCIAL PROPERTIES AND METHOD FOR FORMING SAME**
Patent No:	**7601285**
Issue Date:	**10/13/2009**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-11032-US01

Request for Reconsideration of Patent Term Adjustment, 37 CFR 1.705

The patentee hereby requests reconsideration, under 35 USC 154(d), of the Determination of Patent Term Adjustment (PTA) made by the Director as indicated on the Issue Notification and on the face of US 7601285, issued 10/13/2009, copies of which are attached hereto. Applicant also requests that consideration of this petition be held in abeyance until *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008), currently on appeal, is decided.

Determination of Patent Term Adjustment

As indicated on the face of the patent and on the Issue Notification, the adjustment to patent term is **730** days. Also attached is the PAIR record showing the basis for this determination, which is believed to be incorrect. The correct adjustment is **1122** days.

The above referenced application was filed on December 31, 2003 and so is entitled to the benefit of the current version of 35 U.S.C. 154. The PTA determination fails to follow the calculation method required by law as determined in *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008), currently on appeal to the Federal Circuit, which is controlling law for the issues presented herein.

This Application for PTA constitutes a request that the patent term adjustment be made in accordance with the determination method described in the *Wyeth* case.

(1) This request is accompanied by the fee set forth in 37 CFR § 1.18(e).

(2) This request is being timely filed on or before 12/13/2009. The patent issued 10/13/2009 and the two month date for petitioning the commissioner falls on 12/13/2009. This request could not have been filed prior to the issuance of the patent as the "three year" delay days could not have been determined until the issuance date. To that end, Petitioner notes that a petition filed by this law firm prior to the issue date, in application **10/732983**, was held in abeyance pending issuance of the patent in a decision in which the Office stated:

> As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, a decision is being **held in abeyance** until after the actual patent date. Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.703(b).

and further:

> Rather than file the request for reconsideration of Patent Term Adjustment at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term pursuant to 37 CFR 1.705(d). The USPTO notes that it does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent and accordingly, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.

Therefore it is clear that this request is timely.

(3) Statement of the facts involved:

(i) The correct patent term adjustment and the basis under 37 CFR § 1.702 for the adjustment is as follows:

USPTO delay days to the issuance of the first Office Action as indicated on PAIR	+ 854
Other delay days post-first Office Action as indicated by PAIR	+ 0
Total USPTO delay days as indicated by PAIR	+854
Non-overlapping three year days until filing of RCE (7/03/2007 through 7/28/2008)	+392
Applicant delay days as indicated on PAIR	- 124
Correct Adjustment	**1122**

(ii) The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled are explained as follows:

The Office calculation of 730 days fails to properly include all of the USPTO 3-year delay days. As *Wyeth* establishes, this is improper. No time was consumed by an interference proceeding under 35 U.S.C. 135(a); no time was consumed by the imposition of a secrecy order under 35 U.S.C. 181; by review by the Board of Patent Appeals and Interferences or a Federal court; the patent issued or the first RCE was filed after the 3 year date. Applicant is entitled to an additional adjustment to the patent term based on the USPTO delay subsequent to the three year date that have not otherwise been accounted for as USPTO delay days.

The USPTO delay day period of 854 days ended on 7/02/2007. This was already after the three-year due date (12/31/2006) for patent issuance. Therefore, except for the intervening days of applicant delay, every day after 7/02/2007, until 7/28/2008 the date the RCE was filed, was a non-overlapping three-year day under the *Wyeth* decision. The total period from 7/03/2007 through 7/28/2008, the date of filing of the RCE is 392 days. This is added to the 854 delay days. Then the 124 days of applicant delay are subtracted to yield the correct adjustment of **1122** days.

(iii) The patent is not subject to a terminal disclaimer.

(iv) (A) Applicant has included herewith a copy of the print-out from the USPTO's PAIR Patent Term Adjustment page for the above file in which the USPTO has set forth adjustments made for Applicant's delay. Applicant has not verified the USPTO's determination but accepts it for the purposes of this petition. The circumstances for each downward adjustment may be found on that page.

All items required under 37 CFR 1.705 having been provided herein, the applicant requests that the Patent Term Adjustment be corrected to show an adjustment of **1122** days.

Request to Hold the Decision on this Petition in Abeyance

Applicant also requests that the decision on this petition be held in abeyance pending final adjudication of the *Wyeth* case.

Applicant notes that the USPTO has indicated (in a decision on a petition for reconsideration of the patent term adjustment of a different patent) that it has no regulatory authority to hold such petitions in abeyance. Applicant disagrees on several grounds.

First, the USPTO, as a regulatory agency, is charged with responsibility for decisions regarding the management and administration of its operations. To that end, 35 USC 1(a) states:

> **35 U.S.C. 1 Establishment.**
>
> (a) ESTABLISHMENT.— The United States Patent and Trademark Office is established as an agency of the United States, within the Department of Commerce. In carrying out its functions, the United States Patent and Trademark Office shall be subject to the policy direction of the Secretary of Commerce, but otherwise shall retain responsibility for decisions regarding the management and administration of its operations and shall exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with this title and applicable provisions of law. Those operations designed to grant and issue patents and those operations which are designed to facilitate the registration of trademarks shall be treated as separate operating units within the Office.

The responsibility referred to in 35 USC 1(a) includes assigning case loads and determining when petitions are reviewed. It is not believed that specific regulations are necessary to govern the details of the day-to-day operation of the USPTO. Note that the MPEP

is essentially a compilation of Patent Office procedure, much of which is not expressly provided for under the regulations. As such, even without specific regulatory authority, Applicant contends that it is within the discretion of the USPTO to hold a decision on a petition in abeyance while a controlling legal issue is pending in court, and with the requester's specific consent, given herein.

We further note that the MPEP provides for at least one situation in which a petition may be held in abeyance, not withstanding the lack of specific regulatory authority. MPEP 724.06 states:

> The decision on the petition to expunge should be held in abeyance until the application is allowed or an Ex parte Quayle action, or a Notice of Abandonment is mailed, at which time the petition will be decided. However, where it is clear that the information was submitted in the wrong application, then the decision on the petition should not be held in abeyance.

Note also the quotation on page 2 above from the decision in application **10/732983,** which held a petition for term adjustment in abeyance until the patent had issued. Clearly the Office has authority to hold petitions for patent term adjustment in abeyance when there is a sound reason to do so. There are multiple such sound reasons.

First, efficiency interests of the Office and of the patentees coincide. The *Wyeth* court has already determined that non-overlapping 3-year dates must be taken into account. It makes no sense to force other patentees to file cases under 35 USC §154(b) to preserve their rights. This multiplies litigation defense costs of the Office and unnecessarily increases the patentees expenses in obtaining their patent rights. A simple public announcement that the Office will hold all patent term requests in abeyance until a final decision on the *Wyeth* appeal – and then will decide them all on the basis of that final decision – will allow the USPTO to advance its position in the appeal without harming patentees if the Office is ultimately unsuccessful. Rational workload management considerations within the USPTO and general equitable considerations of fairness to patent owners, both weigh heavily in favor of the Office deferring consideration of any petitions citing the *Wyeth* case until the case has been decided on the appellate level.

Second, the Administrative Procedure Act prohibits agency action that is "not in accordance with law." The *Wyeth* court has ruled the Office's interpretation of §154(d) to be "a

construction cannot be squared with the language of §154(b)(1)(B)." Thus the position of the Office on periods of overlap under 154 is "not in accordance with law" within the meaning of the Administrative Procedure Act. *Unless and until* the Office obtains a reversal of that decision, the Office has no legal authority to decide a petition for term adjustment using the statutory construction advanced by the Office in the *Wyeth* case. Simply deciding to issue a decision on this petition while the *Wyeth* case is on appeal using the Office's construction of §154 that it used in the *Wyeth* case would be arbitrary and capricious, given the fact that the Office is on notice that its construction is wrong as a matter of law. Issuing decisions on grounds already found "contrary to law" would therefore violate the Administrative Procedure Act independent of the stated grounds for the decision.

Finally, this request specifically impacts a property right that the applicant is legally entitled to. The due process clause of the U.S. Constitution is violated when the Office decides to deprive patent owners of term under a statutory construction that has been ruled to be contrary to law.

The correct calculation under the *Wyeth v. Dudas* case yields an adjustment of **1122** days. The Office does not have authority under law or the U.S. Constitution to issue a decision denying this request unless it obtains a reversal of the *Wyeth* case. It has the authority to defer decision on this request. Deferring the decision preserves the Office's interest in advocating its construction to a final adjudication while at the same time respecting the property rights of the patent owner in this case. Good cause has been shown for holding this request in abeyance.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: December 3, 2009

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,821	10/13/2009	7601285	S63.2-11032-US01	9361

490 7590 09/23/2009

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 730 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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Patent Application Information Retrieval

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10/749,821 MEDICAL DEVICE WITH VARYING PHYSICAL PROPERTIES AND METHOD FOR FORMING SAME

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Patent Term Adjustment

Filing or 371(c) Date:	12-31-2003	USPTO Delay (PTO) Delay (days):	854
Issue Date of Patent:	10-13-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	124
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	730
USPTO Adjustment (days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-23-2009	PTA 36 Months		
10-13-2009	Patent Issue Date Used in PTA Calculation		
09-12-2009	Dispatch to FDC		
09-08-2009	Application Is Considered Ready for Issue		
09-01-2009	Issue Fee Payment Verified		
09-01-2009	Issue Fee Payment Received		
06-01-2009	Mail Notice of Allowance		
05-29-2009	Notice of Allowance Data Verification Completed		
05-05-2009	Date Forwarded to Examiner		
05-05-2009	Mail Appeals conf. Reopen Prosec.		
05-05-2009	Pre-Appeals Conference Decision - Reopen Prosecution		
04-10-2009	Request for Pre-Appeal Conference Filed		
04-10-2009	Notice of Appeal Filed		
02-17-2009	Mail Final Rejection (PTOL - 326)		
02-13-2009	Final Rejection		
12-04-2008	Date Forwarded to Examiner		
11-26-2008	Response after Non-Final Action		
09-05-2008	Mail Non-Final Rejection		
09-02-2008	Non-Final Rejection		
07-29-2008	Date Forwarded to Examiner		
07-29-2008	Date Forwarded to Examiner		
07-28-2008	Request for Continued Examination (RCE)		32
07-29-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		
07-28-2008	Request for Extension of Time - Granted		
07-28-2008	Workflow - Request for RCE - Begin		
06-04-2008	Mail Advisory Action (PTOL - 303)		
06-03-2008	Advisory Action (PTOL-303)		
05-16-2008	Date Forwarded to Examiner		
05-15-2008	Amendment after Final Rejection		
03-26-2008	Mail Final Rejection (PTOL - 326)		
03-24-2008	Final Rejection		
01-02-2008	Information Disclosure Statement considered		
01-02-2008	Reference capture on IDS		
01-02-2008	Information Disclosure Statement (IDS) Filed		
01-17-2008	Date Forwarded to Examiner		
01-02-2008	Response after Non-Final Action		92

01-02-2008	Request for Extension of Time - Granted		
01-02-2008	Information Disclosure Statement (IDS) Filed		
10-05-2007	Case Docketed to Examiner in GAU		
07-02-2007	Mail Non-Final Rejection	854	
06-24-2007	Non-Final Rejection		
07-20-2005	Information Disclosure Statement considered		
07-28-2005	Information Disclosure Statement considered		
03-18-2004	Information Disclosure Statement considered		
05-16-2007	Case Docketed to Examiner in GAU		
01-28-2007	Case Docketed to Examiner in GAU		
01-16-2007	Transfer Inquiry to GAU		
09-29-2006	Case Docketed to Examiner in GAU		
09-29-2006	Case Docketed to Examiner in GAU		
07-28-2005	Reference capture on IDS		
07-28-2005	Information Disclosure Statement (IDS) Filed		
07-28-2005	Information Disclosure Statement (IDS) Filed		
07-20-2005	Miscellaneous Incoming Letter		
07-20-2005	Information Disclosure Statement (IDS) Filed		
07-20-2005	Information Disclosure Statement (IDS) Filed		
01-27-2005	IFW TSS Processing by Tech Center Complete		
01-27-2005	Case Docketed to Examiner in GAU		
03-18-2004	Reference capture on IDS		
03-18-2004	Information Disclosure Statement (IDS) Filed		
03-18-2004	Information Disclosure Statement (IDS) Filed		
05-03-2004	Application Return from OIPE		
05-04-2004	Application Is Now Complete		
05-03-2004	Application Return TO OIPE		
05-03-2004	Application Return from OIPE		
05-03-2004	Application Return TO OIPE		
05-03-2004	Application Dispatched from OIPE		
05-03-2004	Application Is Now Complete		
02-26-2004	Cleared by OIPE CSR		
01-24-2004	IFW Scan & PACR Auto Security Review		
12-31-2003	Initial Exam Team nn		

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